

FEB 11 2005

K041940

**510(k) Summary of Safety and Effectiveness for the
ZIRCONIA-TOUGHENED-ALUMINA (BIOLOX® DELTA) CERAMIC
FEMORAL HEADS**

Proprietary Name: Howmedica Osteonics Zirconia-Toughened-Alumina (BioloX® Delta) Ceramic Femoral Heads

Common Name: Artificial Femoral Head Component

Classification Name and Reference: Hip Joint, Metal/Ceramic/Polymer, Semi-Constrained, Cemented or Nonporous Uncemented Prosthesis, 21 CFR §888.3353

Proposed Regulatory Class: Class II

Device Product Code: 87 LZO

Official Contact: Terry Sheridan Powell
Regulatory Affairs Team (Consultant)
Howmedica Osteonics Corp.
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Date Summary Prepared: December 1, 2004

Predicate Devices

The predicate devices cited in this 510(k) application are the Osteonics® Alumina C-Taper Heads cleared under K971409, K991952, and K003391, and the competitive ceramic heads cleared under K031803.

Device Description

The subject Zirconia-Toughened-Alumina (ZTA) Ceramic Femoral Heads feature:

- BioloX® Delta material: this material is a composite of approximately 75% Alumina ceramic, with the balance consisting of zirconium oxide, chromium oxide, and other oxides,

- A C-Taper bore to mate with C-Taper* stems made from Titanium or CoCr alloys,
- Sizes:
 - 28mm diameter with neck lengths of -2.5mm, +0mm, +2.5mm, +5mm,
 - 32mm diameter with neck lengths of -2.5mm, +0mm, +2.5mm, +5mm,
 - 36mm diameter with neck lengths of -2.5mm, +0mm, +2.5mm, +5mm.

Intended Use

The subject devices are single use devices. They are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures. The subject devices are single use devices. They can be used with all Howmedica Osteonics C-Taper* hip stems made from Titanium or CoCr alloys. When used as a total hip replacement, they are intended for use only with Howmedica Osteonics polyethylene bearing surfaces.

Indications for Use as a Bipolar

- Femoral head/neck fractures or non-unions,
- Aseptic necrosis of the femoral head,
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion,
- Pathological conditions or age considerations that indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum,
- Salvage of failed total hip arthroplasty.

Indications for Use as a Total Hip:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results,
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies in the acetabulum.

Substantial Equivalence:*Intended Use:*

The subject devices share the identical *indications for use* as the cited predicate Howmedica Osteonics devices. The *intended use* for the predicate Howmedica Osteonics devices states that they can be used only with C-Taper hip stems made from Titanium alloy. The subject devices, however, can be used with C-Taper* hip stems made from CoCr or Titanium alloys. This is because the subject devices, made from ZTA ceramic, are stronger.

Design:

The subject devices feature the same design as the predicate Howmedica Osteonics devices. They feature the same C-Taper bore, and the same availability in 28mm, 32mm, and 36mm outer

* The term "C-Taper" includes both the original C-Taper design, and the modified C-Taper design first introduced on the hip stems found Substantially Equivalent via K982032.

diameters. The subject devices feature neck length options of -2.5mm, +0mm, +2.5mm, and +5mm (while the predicate devices feature neck length options of -5mm, -2.5mm, +0mm, and +5mm). The subject devices do not feature a new worst-case neck length option—all neck length options fall within the range of neck lengths already cleared for the predicate Howmedica Osteonics devices.

Material:

The subject devices are manufactured from ZTA ceramic material. One of the cited predicate devices is also manufactured from ZTA ceramic material.

Performance Data:

Mechanical testing demonstrated that the subject devices' mechanical properties were substantially equivalent to the predicate devices' mechanical properties.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 11 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K041940

Trade/Device Name: Howmedica Osteonics Zirconia-Toughened-Alumina (BioloX®
Delta) Ceramic Femoral Heads

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or
nonporous uncemented prosthesis

Regulatory Class: II

Product Code: LZO

Dated: January 20, 2005

Received: January 21, 2005

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

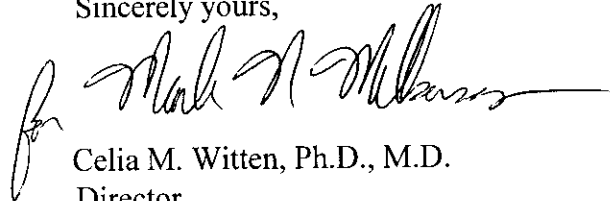
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right. To the left of the signature is a small, stylized mark that looks like a lowercase "f" or a checkmark.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K041940

Device Name: ZTA Ceramic Femoral Heads

Indications for Use:

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Indications for Use as a Bipolar

- Femoral head/neck fractures or non-unions,
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- Salvage of failed total hip arthroplasty

Indications for Use as a Total Hip:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Melanson
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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